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10/755,798	01/12/2004	Susan Legault	706718US1	9383

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EXAMINER	
WEST, JEFFREY R	

ART UNIT	PAPER NUMBER
2857	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/755,798	LEGAULT ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5,22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Response to Amendment

2. The amendment filed January 26, 2006, is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly amended paragraph 0004 describing the method of "the formation of a FMEA team for assigning responsibilities and determining at least one specific existing process appropriate for use in capturing relevant knowledge...A draft FMEA is performed on the new process using learning captured from the gathered data and analyzed differences between the existing and new process. A process specific FMEA is then performed on the new process focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft

FMEA. The FMEA team conducts a group validation of the process specific FMEA to detect and eliminate problems between steps of the new process. Management then reviews the validated process specific FMEA, and the approved process specific FMEA is forwarded to a facility where the new process will be performed for use in taking preventative action to prevent potential failures in an order determined by results of the process specific FMEA."

Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

3. The drawings are objected to because of the following informalities:

In Figure 7, "8.0 CONDUCT LINE TALKS" should be ---6.0 CONDUCT LINE TALKS---.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be

necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 3, 5, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 22 fails to comply with the written description requirement because it recites "forming a FMEA team for assigning responsibilities and determining at least one specific existing process appropriate for use in capturing relevant knowledge...performing a draft FMEA on the new process using learning captured from the gathered data and analyzed differences between the existing and new

processes; performing a process specific FMEA on the new process focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft FMEA; conducing a FMEA team group validation of the process specific FMEA to detect and eliminate problems between steps of the new process; and conducting a management review of a validated process specific FMEA and, upon management approval, forwarding the validated process specific FMEA to a facility where the new process will be conducted for use in taking preventive action to prevent potential failures in an order determined by results of the process specific FMEA."

First, while the instant disclosure as originally filed does support "forming a FMEA team", there is no supporting disclosure for using the FMEA team for "assigning responsibilities and determining at least one specific existing process appropriate for use in capturing relevant knowledge." Instead, the instant disclosure specifies "[r]eviewing previous failure mode and effects analysis 22 generally includes compiling previously completed failure mode and effects analyses from either the same process being analyzed or from similar processes" (instant specification, paragraph 0018, lines 1-3) without a specific team determining a specific process.

Second, the instant disclosure as originally filed does not support performing both a draft FMEA and a process specific FMEA on the new process with the

process specific FMEA "focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft FMEA".

In paragraph 0024, lines 1-3, and paragraph 0028, lines 3-4, the instant disclosure indicates that the FMEA is performed at step 16.

The instant disclosure also discusses drafting a FMEA in paragraph 0029:

> Specifically, reviewing the previous failure mode and effects analyses 22 includes focusing on finding process controls, including preventive measures (e.g., preventive maintenance, quality checks, inspection), error proofing and mistake proofing devices. These will be documented and retained for use in drafting the failure mode and effects analysis at step 14. The previous failure mode and effects analysis should also be reviewed for component parts, limited to those that substantially impact the process being analyzed. Previous tasks with high risk priority numbers and especially tasks with high detection ratings should be identified, documented and retained for use in the draft of the failure mode and effects analysis at step 14. Part design failure mode and effects analysis should also be reviewed to identify high risk priority number items, especially items with high severity ratings. These should be documented and retained for use in the draft of the failure mode and effects analysis at step 14. Finally, any historical equipment information available from the supplier, such as equipment capability studies and failure mode effects analysis, should be reviewed to identify potential equipment failures. Again, these should be documented and retained for use in the draft of the failure mode and effects analysis at step 14.

As seen from the instant disclosure, this drafting of a FMEA is performed at step 14 and, turning to Figure 1, it is this FMEA determined at step 14 that is used to perform the FMEA at step 16.

The disclosure for performing the FMEA is discussed in the instant disclosure in paragraph 0035:

> The second entity 20 convenes at step 16 to conduct the failure mode and effects analysis. The second entity 20 should include (for manufacturing processes as an example) tool engineers, plant/facilities engineers, controls engineers, supervisors, industrial engineers, product engineers, tool/process and resident engineers from the plant, plant controls engineers, plant quality

> engineers, plant engineering supervisors, production operators, job setters, skilled trades, supplier project leaders and engineering teams, and any facilitators directed by management. During the meeting, introductory failure mode and effects analysis training is performed. Significant processes/product differences are defined, review of the overall flow of the section under review of the process under review is performed, and a line by line review of the tasks listed in the potential failure mode and effects analysis form (FIG. 4) is completed. Potential defects are documented, occurrence and detection ratings are assigned and the risk priority number is calculated. Error proofing and mistake proofing are then brainstormed to reduce any high risk priority number items. Then responsibilities and target dates for any recommended actions are assigned.

As seen from the instant disclosure, this performance of the FMEA is conducted at step 16, and turning to Figure 1, it is the result of the FMEA determined at step 14 that is performed at step 16. As noted above, the FMEA determined at step 14 corresponds to the draft FMEA.

The Examiner notes that Figure 7 does illustrate step 14 as "CONDUCT DRAFT PFMEA" and step 16 as "CONDUCT OPERATION SPECIFIC PFMEA". However, as noted above and throughout the specification, step 14 is clearly the step of identifying potential failures. Therefore, as may best be understood by one having ordinary skill in the art, the step of "CONDUCT DRAFT PFMEA" does not correspond to performing a draft FMEA on the new process, but instead for drafting a PFMEA by identifying potential failures, as supported by paragraph 0029. Then the subsequent step of "CONDUCT OPERATION SPECIFIC PFMEA", corresponding to step 16, is conducing the FMEA updated with operation specific information, as supported by paragraph 0035.

Therefore, the instant disclosure as originally filed does not provide support for performing both a draft FMEA and a process specific FMEA on the new process with

the process specific FMEA "focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft FMEA".

Third, the instant disclosure as originally filed does not support "conducting a FMEA team group validation of the process specific FMEA to detect and eliminate problems between steps of the new process." The instant disclosure does support conducting a FMEA team group validation of the process specific FMEA and paragraph 0034 states:

> The second step of identifying potential failures 14 of the method 10 is then performed by the first entity 18, as described above. During step 14, the first entity 18 should include tool and/or plant engineer leaders, product engineers, plant resident engineers, and any facilitators directed by management. The significant differences will be reviewed. The documented process steps and functional requirements for the entire failure mode and effects analysis will be reviewed, major issues will be identified and listed in the failure mode and effects analysis form (FIG. 4) and the customer impact of potential problems will be described as well as severity rankings established for each.

However, this disclosure falls short of providing adequate support for the detection and elimination of problems between steps of the new process.

Fourth, the instant disclosure as originally filed does not support "forwarding the validated process specific FMEA to a facility where the new process will be conducted for use in taking preventive action to prevent potential failures in an order determined by results of the process specific FMEA."

In the instant disclosure, paragraph 0037 specifies:

> At step 106, upper level management reviews the completed and finalized failure mode and effects analysis, as well as any corrective action that has or is being performed. If management does not accept the completed failure mode and effects analysis at step 108, the group validation at step 104 must be performed again. If, however, management is satisfied with the completed failure mode and effects analysis at step 108, then at step 110 the failure mode effects analysis is posted for all to review and use. Moreover, continuing corrective action is performed on all listed potential failures.

As best understood from this section of the disclosure and in light of the limitations as claimed, it is the "validated process specific FMEA" results that are used in taking preventive action to prevent potential failures rather than the "process specific FMEA" as claimed.

Claims 2, 3, 5, and 23 are rejected under 35 U.S.C. 112, first paragraph, because they incorporate the lack of written description of parent claim 22.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 5, 22, and 23, as may best be understood, are rejected under 35 U.S.C.

103(a) as being unpatentable over U.S. Patent Application Publication No. 2004/0225475 to Johnson et al. in view of U.S. Patent No. 6,959,235 to Abdel-Malek et al.

With respect to claim 22, Johnson discloses a method for systematically capturing knowledge and applying the knowledge to assist in performing a failure mode and effects analysis (FMEA) on a new process (0014, lines 1-4 and 0030, lines 30-37), the method comprising forming a FMEA team for assigning responsibilities and determining a new appropriate process for use in capturing relevant knowledge (0016, lines 3-9 and 0023, lines 1-18), gathering data from the new process relating to actual failures (0026, lines 1-8), their causes and known solutions for correcting the actual failures (0026, lines 16-20), performing a draft FMEA on the new process using learning captured from the gathered data (0026, lines 16-30), performing a process specific FMEA on the new process focusing on high priority issues (i.e. high priority reported/detected complaints/failures) having greatest impact on quality identified using the draft FMEA (0027, lines 1-20), conducing a FMEA team group validation of the process specific FMEA to detect and eliminate problems between steps of the new process (0027, lines 20-26 and 0030, lines 30-37), conducting a management review of a validated process specific FMEA (0024, lines 4-24 and 0027, lines 26-31) and, upon management approval, forwarding the validated process specific FMEA to a facility where the new process will be conducted for use in taking preventive action to prevent potential failures in

an order determined by results of the process specific FMEA (0022, lines 22-24, 0024, lines 11-24, and 0025, lines 1-24).

With respect to claim 23, Johnson discloses returning the validated process specific FMEA to the FMEA team for revision and revalidation whenever management approval is not obtained (i.e. the owner makes suggestions to the FMEA team for combing lines and discussions of the combinations to revise and revalidate the FMEA) (0024, lines 1-8).

As noted above, the invention of Johnson teaches many of the features of the claimed invention and while the invention of Johnson does teach providing potential failures for developing and performing a draft FMEA, Johnson does not specify that the potential failures be provided by gathering data from an existing related process and using the potential failures from the existing related process with differences between the existing related process and the new process to perform the FMEA.

Abdel-Malek teaches a diagnosis and repair system and method for a current system comprising gathering potential failure data from at least one existing related system relating to actual failures, their causes and known solutions for correcting the actual failures (column 3, lines 21-22 and column 27, lines 33-60), analyzing differences between the at least one existing related system and the current system to identify potential adverse impacts on quality (i.e. determine differences between current and related repair trends to determine potential failures/repairs) (column 7, lines 49-64), and performing failure analysis using the gathered data and analyzed differences (column 3, lines 15-29).

It would have been obvious to one having ordinary skill in the art to modify the invention of Johnson to specify that the potential failures be provided by gathering data from an existing related process and using the potential failures from the existing related process with differences between the existing related process and the new process to perform the FMEA, as taught by Abdel-Malek, because, as suggested by Abdel-Malek, the combination would have provided a method for providing the potential failures, as required by Johnson, in a manner that would have included a more accurate prediction of the type of failures that might occur in the current system by using actual data from a related system undergoing similar conditions (column 2, lines 10-17 and column 3, lines 15-29) and comparing the differences between the current and related systems to determined when such potential failures are most likely to occur (column 7, lines 49-64).

With respect to claim 5, since the invention of Abdel-Malek teaches determining differences between current and related repair trends to determine potential adverse impacts (i.e. failures/repairs) (Abdel-Malek; column 7, lines 49-64) and Johnson teaches quantifying a severity associated with each of the potential failures (Johnson; 0024, lines 11-24) the combination of Johnson and Abdel-Malek teaches that the step of analyzing differences further comprises quantifying a severity associated with each potential adverse impact.

9. Claims 2 and 3, as may best be understood, are rejected under 35 U.S.C. 103(a)

as being unpatentable over Johnson et al. in view of Abdel-Malek et al. and further in view of U.S. Patent No. 6,643,592 to Loman et al.

As noted above, the invention of Johnson and Abdel-Malek teaches many of the features of the claimed invention and while the invention of Johnson and Abdel-Malek does teach gathering data from an existing similar process; the combination does not explicitly state that the data be gathered from an existing similar process by interviewing workers at the existing similar process.

Loman teaches a system and method for fault diagnosis comprising a first entity that gathers data from (i.e. at the location of) a similar/existing process/machine by interviewing workers associated with the process/machine and, using such information, attempts to determine a potential fault (column 3, lines 49-55).

It would have been obvious to one having ordinary skill in the art to modify the invention of Johnson and Abdel-Malek to explicitly state that the data be gathered from an existing similar process by interviewing workers at the existing similar process, as taught by Loman, because Loman suggests that the combination would have improved the diagnosis and any repair of the machine/process by allowing the first entity to use a wider variety of information including past experiences with the machine/process to determine any potential problems (column 1, lines 41-51) as well as information from those most readily exposed to, and therefore having expert knowledge of, the machine/process operation (column 3, lines 49-55).

Response to Arguments

10. Applicant's arguments filed June 28, 2006, have been fully considered but they are not persuasive.

Applicant argues in response to the objection under 35 U.S.C. § 132:

> Paragraph [0004] is based on Claim 22, and, for the reasons set forth below in more detail below, is supported by originally submitted Fig. 7 and the Specification beginning at Paragraph [0027]. Withdrawal of the objection is requested.

The Examiner maintains the new matter objection for reasons provided below with respect to Applicant's arguments regarding the lack of written description.

Applicant argues in response to the rejection under 35 U.S.C. § 112:

> As noted at § 2163.06, Manual of Patent Examining Procedure, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter. Independent Claim 22 finds clear support in Fig. 7 and the specification. Each limitation cited by the Examiner is discussed below seriatim.
>
> - "forming a FMEA team for assigning responsibilities in determining at least one specific existing process appropriate for use in capturing relevant knowledge."
>
> A specific team determining a specific existing process is inherent in reviewing previous failure mode and effects analysis.
>
> Capturing relevant knowledge of the determined existing process is shown at level 12 of Fig. 7 and includes blocks 3.0—7.0.

The Examiner first asserts that a specific team determining a specific existing process is not inherent in reviewing previous failure mode and effect analysis since one having ordinary skill in the art would recognize that such specific process determination can be made by an individual, rather than a team, or by an automated process requiring no team interaction.

The Examiner also asserts that blocks 3.0—7.0 state:

"3.0 Review Previous FMEA; 4.0 Review Improved Items; 5.0 Review SQDCM Results; [6].0 Conduct Line Talks; 7.0 Analyze Significant Differences; 8.0 Conduct Draft PFMEA".

These blocks additionally do not provide supporting disclosure for using the FMEA team for "assigning responsibilities and determining at least one specific existing process appropriate for use in capturing relevant knowledge."

Therefore, the Examiner maintains that while the instant disclosure as originally filed does support "forming a FMEA team", there is no supporting disclosure for using the FMEA team for "assigning responsibilities and determining at least one specific existing process appropriate for use in capturing relevant knowledge." Instead, the instant disclosure specifies "[r]eviewing previous failure mode and effects analysis 22 generally includes compiling previously completed failure mode and effects analyses from either the same process being analyzed or from similar processes" (instant specification, paragraph 0018, lines 1-3) without a specific team determining a specific process.

Applicant argues:

- "performing a draft FMEA on the new process using learning captured from the gathered data and analyze the differences between the existing and new processes"

This is shown as block 14 of Fig. 7. Also, see the Specification at Paragraph [0029].

- "performing a process specific FMEA on the new process focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft FMEA"

This is shown as block 16 of Fig. 7. Also, see the Specification at Paragraph [0035].

The Examiner asserts that block 14 states, "8.0 Conduct Draft PFMEA"; block 16 states, "9.0 Conduct Operation Specific PFEMA"; and paragraphs 0029 and 0035 state:

> [0029] Specifically, reviewing the previous failure mode and effects analyses 22 includes focusing on finding process controls, including preventive measures (e.g., preventive maintenance, quality checks, inspection), error proofing and mistake proofing devices. These will be documented and retained for use in drafting the failure mode and effects analysis at step 14. The previous failure mode and effects analysis should also be reviewed for component parts, limited to those that substantially impact the process being analyzed. Previous tasks with high risk priority numbers and especially tasks with high detection ratings should be identified, documented and retained for use in the draft of the failure mode and effects analysis at step 14. Part design failure mode and effects analysis should also be reviewed to identify high risk priority number items, especially items with high severity ratings. These should be documented and retained for use in the draft of the failure mode and effects analysis at step 14. Finally, any historical equipment information available from the supplier, such as equipment capability studies and failure mode effects analysis, should be reviewed to identify potential equipment failures. Again, these should be documented and retained for use in the draft of the failure mode and effects analysis at step 14.
>
> [0035] The second entity 20 convenes at step 16 to conduct the failure mode and effects analysis. The second entity 20 should include (for manufacturing processes as an example) tool engineers, plant/facilities engineers, controls engineers, supervisors, industrial engineers, product engineers, tool/process and resident engineers from the plant, plant controls engineers, plant quality engineers, plant engineering supervisors, production operators, job setters, skilled trades, supplier project leaders and engineering teams, and any facilitators directed by management. During the meeting, introductory failure mode and effects analysis training is performed. Significant processes/product differences are defined, review of the overall flow of the section under review of the process under review is performed, and a line by line review of the tasks listed in the potential failure mode and effects analysis form (FIG. 4) is completed. Potential defects are documented, occurrence and detection ratings are assigned and the risk priority number is calculated. Error proofing and

mistake proofing are then brainstormed to reduce any high risk priority number items. Then responsibilities and target dates for any recommended actions are assigned.

The Examiner maintains that the instant disclosure as originally filed does not support performing both a draft FMEA and a process specific FMEA on the new process with the process specific FMEA "focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft FMEA".

In paragraph 0024, lines 1-3, and paragraph 0028, lines 3-4, the instant disclosure indicates that the FMEA is performed at step 16.

The instant disclosure also discusses drafting a FMEA in paragraph 0029 which specifically indicates that this drafting of a FMEA is performed at step 14 and, turning to Figure 1, it is this FMEA determined at step 14 that is used to perform the FMEA at step 16.

The disclosure for performing the FMEA is discussed in the instant disclosure in paragraph 0035 and specifically this performance of the FMEA is conducted at step 16, and turning to Figure 1, it is the result of the FMEA determined at step 14 that is performed at step 16. As noted above, the FMEA determined at step 14 corresponds to the draft FMEA.

The Examiner notes that Figure 7 does illustrate step 14 as "CONDUCT DRAFT PFMEA" and step 16 as "CONDUCT OPERATION SPECIFIC PFMEA". However, as noted above and throughout the specification, step 14 is clearly the step of

identifying potential failures. Therefore, as may best be understood by one having ordinary skill in the art, the step of "CONDUCT DRAFT PFMEA" does not correspond to performing a draft FMEA on the new process, but instead for drafting a PFMEA by identifying potential failures, as supported by paragraph 0029. Then the subsequent step of "CONDUCT OPERATION SPECIFIC PFMEA", corresponding to step 16, is conducing the FMEA updated with operation specific information, as supported by paragraph 0035.

Therefore, the instant disclosure as originally filed does not provide support for performing both a draft FMEA and a process specific FMEA on the new process with the process specific FMEA "focusing on high priority issues having greatest impact on safety, quality, delivery, cost or morale identified using the draft FMEA".

Applicant argues:

- "conducting a FMEA team group validation of the process specific FMEA to detect and eliminate problems between steps of the new process"

This is shown as block 104 of Fig. 7. Also, see the Specification at Paragraph [0036].

The Examiner asserts that block 104 states, "10.0 Conduct Group Validation" and paragraph 0036 states:

[0036] Once step 16 is completed, a group validation is performed on the failure mode and effects analysis at step 104. The group validation focuses on reviewing the completed failure mode and effects analysis and making sure that it is fully integrated. Also, group validation links separate failure mode effects analysis's performed on separate components or processes, thereby assuring that separate corrective or preventive measures taken do not conflict with one

another. Transport or handling done between the processes are examined for potential failures or deficiencies at this step.

The Examiner maintains that the instant disclosure as originally filed does not support "conducting a FMEA team group validation of the process specific FMEA to detect and eliminate problems between steps of the new process." The instant disclosure does support conducting a FMEA team group validation of the process specific FMEA but step 10.0 of "Conduct Group Validation" and paragraph 0036 falls short of providing adequate support for the detection and elimination of problems between steps of the new process.

Applicant argues:

- "conducting a management review of a validated process specific FMEA and, upon management approval, forwarding the process specific FMEA to a facility where the new process will be conducted for use in taking preventive action to prevent potential failure as in an order determined by results of the process specific FMEA"

This is shown in blocks 106, 108 and 110 of Fig. 7. Also, see the Specification at Paragraph [0037].

The Examiner asserts that blocks 106, 108, and 110 state, "11.0 Management Review/Corrective Action; Accepted?; Continue Updating, Deliver to the Plant" and paragraph 0037 states:

[0037] At step 106, upper level management reviews the completed and finalized failure mode and effects analysis, as well as any corrective action that has or is being performed. If management does not accept the completed failure mode and effects analysis at step 108, the group validation at step 104 must be performed again. If, however, management is satisfied with the completed failure mode and effects analysis at step 108, then at step 110 the failure mode effects

analysis is posted for all to review and use. Moreover, continuing corrective action is performed on all listed potential failures.

The Examiner maintains that the instant disclosure as originally filed does not support "forwarding the validated process specific FMEA to a facility where the new process will be conducted for use in taking preventive action to prevent potential failures in an order determined by results of the process specific FMEA."

As best understood from paragraph 0037 of the disclosure and in light of the limitations as claimed, it is the "validated process specific FMEA" results that are used in taking preventive action to prevent potential failures rather than the "process specific FMEA" as claimed.

Applicant argues with respect to the rejection under 35 U.S.C. § 103:

> Abdel-Malek et al. discloses a diagnosis and repair system and method for application by field service repairmen to a product in service, not to an improved method for performing FMEA by design, manufacturing and operation personnel on a new process for producing products, as is the case with Applicants' invention.
>
> Applicants' invention is used at the concept phase of a new product generation. Abdel-Malek et al. is directed to use by technicians on a previous product that has already been in production (in this case railroad locomotive) failing in the field. In other words, FMEA, as improved by Applicants' invention, is intended to minimize or prevent potential failures, while Abdel-Makel et al. is concerned with repairing actual filed failures. As such, Applicants' invention is pro-active, while Abdel-Malek et al. (and to a great extent Johnson, et al.) is reactive. Independent Claim 22 and its independent Claims 5 and 23 are therefore believed to be in condition for allowance.

The Examiner asserts that the primary invention of Johnson already teaches forwarding a process specific FMEA to a facility where the new process will be

conducted for use in taking preventive action to prevent potential failures in an order determined by results of the process specific FMEA (0022, lines 22-24, 0024, lines 11-24, and 0025, lines 1-24).

The Examiner also asserts that the invention of Abdel-Malek is only included to modify the invention of Johnson, which already teaches providing potential failures for developing and performing a draft FMEA, to specify that the potential failures be provided by gathering data from an existing related process and using the potential failures from the existing related process with differences between the existing related process and the new process to perform the FMEA

Abdel-Malek then teaches a diagnosis and repair system and method for a current system comprising gathering potential failure data from at least one existing related system relating to actual failures, their causes and known solutions for correcting the actual failures (column 3, lines 21-22 and column 27, lines 33-60), analyzing differences between the at least one existing related system and the current system to identify potential adverse impacts on quality (i.e. determine differences between current and related repair trends to determine potential failures/repairs) (column 7, lines 49-64), and performing failure analysis using the gathered data and analyzed differences (column 3, lines 15-29).

The Examiner also asserts that it would have been obvious to one having ordinary skill in the art to modify the invention of Johnson to specify that the potential failures be provided by gathering data from an existing related process and using the potential failures from the existing related process with differences between the

existing related process and the new process to perform the FMEA, as taught by Abdel-Malek, because, as suggested by Abdel-Malek, the combination would have provided a method for providing the potential failures, as required by Johnson, in a manner that would have included a more accurate prediction of the type of failures that might occur in the current system by using actual data from a related system undergoing similar conditions (column 2, lines 10-17 and column 3, lines 15-29) and comparing the differences between the current and related systems to determined when such potential failures are most likely to occur (column 7, lines 49-64).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Crow, "Failure Modes and Effects Analysis (FMEA)" teaches methods for implementing FMEA in a production environment.

U.S. Patent No. 5,586,252 to Barnard et al. teaches a system for Failure Mode and Effects Analysis.

Rotondaro et al., "Using Failure Mode Effect Analysis (FMEA) to Improve Service Quality Service Operations Management" teaches the use of FMEA as a prevention tool for quality purposes.

U.S. Patent Application Publication No. 2004/0128108 to Cutuli et al. teaches design failure mode effect analysis including the step of identifying potential failures comprising quantifying a severity associated with each potential failure, quantifying

an occurrence ranking associated with each potential failure, quantifying a detection ranking associated with each potential failure and calculating a risk priority number from the severity, occurrence ranking, and detection ranking.

U.S. Patent No. 5,433,245 to Prather et al. teaches an online valve diagnostic monitoring system having diagnostic couplings including means for comparing similar operational units in different plants to identify generic problems with units in particular applications or from a particular manufacturer.

U.S. Patent No. 6,434,458 to Laguer-Diaz et al. teaches a method and apparatus for vehicle data transfer optimization including a well-known system for analyzing data patterns or fault occurrences with respect to the operation of other similar devices under monitoring in order to determine if preventive maintenance is needed on a current device under monitoring to prevent the occurrence of a line-of-service breakdowns since a fault in one device will more than likely occur in another similar device undergoing the same wear/usage.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (571)272-2226. The examiner can normally be reached on Monday through Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (571)272-2216. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey R. West
Examiner – AU 2857

September 18, 2006

MARC S. HOFF
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